

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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In re: ZYPREXA PRODUCTS LIABILITY
LITIGATION
-----X

WILLIAM LEGGETT,

Plaintiff,

-against-

ELI LILLY & COMPANY,

Defendant.
-----X

VENICA PRUETT,

Plaintiff,

-against-

ELI LILLY & COMPANY,

Defendant.
-----X

WILLIAM ASBURY,

Plaintiff,

-against-

ELI LILLY & COMPANY,

Defendant.
-----X

-----X
TYNESHA BELCHER, ERNESTINE
MISOURIA, MILTON NEAL, CECILIA
GUILLEN, ERIC FULLER, and
JOHN BLUME, *in*

TYNESHA BELCHER, ET AL.,

Plaintiffs,

MEMORANDUM & ORDER
DISQUALIFYING EXPERT

04-MD-1596

06-CV-5115

07-CV-1931

06-CV-1593

06-CV-2782

FILED
IN CLERK'S OFFICE
U.S. DISTRICT COURT
★ MAY 12 2009
BROOKLYN OFFICE



-against-

ELI LILLY & COMPANY,

Defendant.

-----X
DARLENE KING-WASHINGTON,
JUDITH GOVE, and JAMES HEAD, *in*

YOLAND CHAVEZ, ET AL.,

Plaintiffs,

06-CV-2592

-against-

ELI LILLY & COMPANY,

Defendant.

-----X
RICHARD LEE COCKLIN, SR.,

Plaintiff,

07-CV-2669

-against-

ELI LILLY & COMPANY,

Defendant.

-----X
DWIGHT L. DEAN,

Plaintiff,

07-CV-4505

-against-

ELI LILLY & COMPANY,

Defendant.

-----X
ROBERT GRIFFITH,

Plaintiff,

06-CV-6888

-against-

ELI LILLY & COMPANY,

Defendant.

-----X
SONIA QUIRARTE, INDIVIDUALLY AND
AS ADMINISTRATOR OF THE ESTATE
OF DANIEL RESENDEZ,

Plaintiff,

07-CV-1161

-against-

ELI LILLY & COMPANY,

Defendant.

-----X
JOHN MORRISON,

Plaintiff,

08-CV-307

-against-

ELI LILLY & COMPANY,

Defendant.

-----X
WILLIAM KNIGHT,

Plaintiff,

06-CV-6894

-against-

ELI LILLY & COMPANY,

Defendant.

-----X
ERIN WILLIAMS,

Plaintiff,

07-CV-3914

-against-

ELI LILLY & COMPANY,

Defendant.

-----X
ROBERT C. CERRATO, JR.,

Plaintiff,

07-CV-3609

-against-

ELI LILLY & COMPANY,

Defendant.

-----X

Jack B. Weinstein, Senior United States District Judge:

I. Introduction

Defendant Lilly produced and marketed Zyprexa, a drug widely used in the treatment of psychiatric problems. It allegedly has the effect of causing excessive weight gain, leading to health problems, most commonly diabetes. A failure to adequately warn is the basis for a number of individual-plaintiff suits now pending in this court. Plaintiffs propose to call Stephen J. Hamburger, M.D., to prove the specific causal relationship between the Zyprexa ingested by these plaintiffs and the onset or worsening of their diabetes. Defendant moves to preclude his proposed testimony for failure to comply with Rule 702 of the Federal Rules of Evidence.

The admissibility of expert testimony in this multi-district litigation has been discussed extensively in connection with a previous round of summary judgment motions. *See Souther, et al. v. Eli Lilly & Company*, 489 F. Supp. 2d 230, 281-85 (E.D.N.Y. 2007). At that time, the court emphasized the flexible analysis required in ruling on expert challenges, with the ultimate goal of assuring that proffered expert testimony meets scientific standards and is relevant and reliable. *See id.* at 282 (citing *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 594-95 (1993)). All experts for both sides were approved in *Souther*. *Id.* at 285-90.

The present motion has been thoroughly briefed by both sides, with thousands of pages of supporting documents, including extensive depositions of Dr. Hamburger in twenty plaintiffs'

cases to which his proposed testimony was critical. An extensive evidentiary hearing was conducted at which Dr. Hamburger was examined at length. Post-hearing briefs were provided.

For the reasons stated below, defendant's motion to preclude the testimony of Dr. Hamburger is granted.

II. Law

Rule 702 of the Federal Rules of Evidence, embodying the basic principles of *Daubert* by requiring adequate data, reliable scientific principles and methods, and the application of the principles to the data, provides the framework for the present analysis:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Determining the admissibility of expert testimony is a role assigned to the district court. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). A suitably thorough inquiry before reaching its determinations is required. *Id.*

The parties are aware of the analytical criteria required by Rule 702. They include: (1) a "liberal standard of admissibility," *see Nimely v. City of New York*, 414 F.3d 381, 395-96 (2d Cir. 2005); (2) necessary educational and experiential qualifications of the proposed expert warranting admissibility, *see Stagl v. Delta Airlines, Inc.*, 117 F.3d 76, 80 (2d Cir. 1997); *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995); (3) helpfulness to the jury, *see Daubert*, 509 U.S. at 591; *United States v. Mulder*, 273 F.3d 91, 101-02 (2d Cir. 2001), and relevance, *see Fed. R. Evid.* 401; (4) Rule 403 balancing to assess "whether the probative value of the proffered evidence substantially outweighs its danger of unfair prejudice," *United States v.*

Jakobetz, 955 F.2d 786, 794 (2d Cir. 1992); *Nimely*, 414 F.3d at 397; Fed. R. Evid. 403; and (5) reliability and scientific validity of the proffered testimony, *see Daubert*, 509 U.S. at 592; *Liriano v. Hobart Corp.*, 949 F. Supp. 171, 177 (S.D.N.Y. 1996).

In this longstanding and highly complex litigation, it is appropriate to place particular emphasis on the reliability and scientific validity of the expert's opinions. *See Souther*, 689 F. Supp. 2d at 283 ("The most challenging and controversial gatekeeping role . . . is that of ascertaining the reliability of proffered testimony, or 'whether the reasoning or methodology underlying the testimony is scientifically valid.'") (quoting *Daubert*, 509 U.S. at 592). At this advanced stage of the *Zyprexa* litigation, with greater knowledge about the benefits and risks of anti-psychotic drugs like *Zyprexa* within the scientific community, precision with respect to the relevant scientific knowledge and its application to the facts of individual cases is expected. An expert's testimony must employ the "same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho*, 526 U.S. at 152.

As previously announced in this *Zyprexa* litigation, there must be evidence of "a sufficiently rigorous analytical connection between [the expert's] methodology and the expert's conclusions." *Souther*, 689 F. Supp. 2d at 284 (quoting *Nimely*, 414 F.3d at 397). Assessed must be whether scientific principles and methods have been reliably applied by the proposed expert to the facts of the case. *Id.* An expert opinion based on insufficient facts, unsupported suppositions, or unreliable methodologies is not acceptable. *See* Fed. R. Evid. 702(1) and (2); *Amorgianos v. National R. R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002) (trial court's *Daubert* analysis requires assessment of "the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand").

Subjective or intuitive guesswork, as well as testimony that is insufficiently connected to the facts of the case, are grounds for rejection of a proffered expert's testimony. *See O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090, 1105-07 (7th Cir. 1994); *Guidroz-Brault v. Missouri Pacific R. R. Co.*, 254 F.3d 825, 831 (9th Cir. 2001). Sound scientific methodology requires a scholar to attempt to account for alternative explanations to his or her findings on causation. *See Kudabeck v. Kroger Co.*, 338 F.3d 856, 860-61 (8th Cir. 2003); *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1256-57 (11th Cir. 2002).

When a prospective expert witness is "unable to articulate any scientific methodology for assessing whether, and to what extent," a drug has contributed to a plaintiff's "weight gain and diabetes, ultimately forcing [him] to draw an entirely speculative conclusion" about the drug's role in the alleged medical injury, the specific causation opinion lacks sufficient reliability under *Daubert* and Rule 702, and must be excluded. *See Guinn v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1239, 1243 (M.D. Fla. 2009); *see also Haller v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1271, 1278-79 (M.D. Fla. 2009) (disqualifying plaintiff's expert in prescription drug action similar to the *Zyprexa* litigation on the ground that the proffered expert opinion that the drug caused the development of diabetes in the plaintiff was based only on the "temporal relationship between [his] taking [the drug] and his subsequent weight gain, and the weight gain's temporal relationship with the development of diabetes"). A medical expert must adequately consider possible alternative causes of an alleged disease, avoiding speculative analysis that automatically implicates a drug in the temporal chain. *See Haller*, 598 F. Supp. 2d at 1299, n.263 (citing Mary Sue Henefin, et al., Reference Guide on Medical Testimony, in Reference Manual On Scientific Evidence 476 (Federal Judicial Center, 2d ed. 2000)).

III. Application of Law to Facts

In most cases, the question of veracity and weight of the proposed opinion should be left to the jury where, as here, the proposed expert has sufficient paper credentials indicating Board certification in the treatment of the disease in question, with clinical experience, medical teaching and supervisory experience. *See* Fed. R. Evid. 702 (“a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion”); *McCulloch*, 61 F.3d at 1044 (assertions that the witness lacks particular educational or other experiential background, “go to the weight, not the admissibility, of [an expert’s] testimony”). Dr. Hamburger meets the necessary educational and experiential qualifications warranting admissibility of his expert testimony. In other respects, the proffered testimony lacks scientific reliability.

The submission of Dr. Hamburger that Zyprexa had a direct adverse effect on cells essential to the production of insulin by the body in cases in which there was no documented weight gain lacks scientific support. The record demonstrates that Dr. Hamburger’s opinions rely on a subjective methodology, a fast and loose application of his scientific theories to the facts, and conclusion-driven assessments on the issues of causation in the cases on which he proposes to testify. He cannot be allowed to testify because his opinions are neither “based upon sufficient facts or data,” nor are they “the product of reliable principles and methods,” and he has not “applied the principles and methods reliably to the facts of the case.” Fed. R. Evid. 702; *cf.* *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (opinion that “is connected to existing data only by the *ipse dixit* of the expert” need not be admitted).

Dr. Hamburger’s conclusion on general causation that use of Zyprexa may lead to excessive weight gain, which in turn may cause diabetes, is well supported by “sufficient facts or data,” and is “the product of reliable principles and methods.” Fed. R. Evid. 702(1) and (2). He

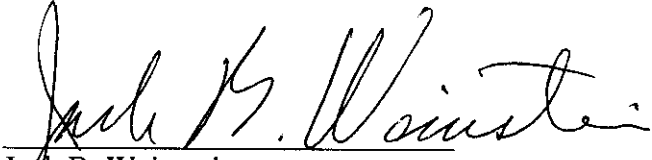
has not, however, “applied the[se] principles and methods reliably to the facts of the case.” Fed. R. Evid. 702(3). He has been shockingly careless about the facts in the cases he proposes to opine about: whether weight gain preceded or followed use of Zyprexa, whether there was weight gain at all, the scientific basis for the claimed causal link between Zyprexa intake and medical injury, and the like. Faced under oath with consistent extensive factual discrepancies in his analyses, he merely shrugged them off or flippantly shifted to new theories and explanations to establish causal relationships. He repeatedly and impermissibly stretched the truth to support findings of causality.

Dr. Hamburger’s pattern of disregard of facts and theory mandate his rejection as an expert in all these cases. The court cannot permit a major pharmaceutical litigation to become the subject of the kind of “rubber-stamp” expert opinions that have so marred mass litigations such as those involving asbestos and breast implants. To allow Dr. Hamburger to testify in these *Zyprexa* cases would negate the struggle of the Supreme Court in cases like *Daubert* and *Kumho*, and of many individuals, to improve the utilization of science by the law. *See, e.g.*, Fed. R. Evid. 702 advisory committee notes (2000).

IV. Conclusion

The motion to disqualify Dr. Stephen J. Hamburger as an expert in the above-captioned cases is granted.

SO ORDERED.


Jack B. Weinstein
Senior United States District Judge

Date: May 12, 2009
Brooklyn, New York